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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/675,106	03/25/91	MORRISON	BP-1-CIP-FWC

NISBET, J.	EXAMINER
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ART UNIT	PAPER NUMBER
185	18

DATE MAILED:

07/03/91

This is a communication from the examiner in charge of your application
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on March 25, 1991
May 20, 1991 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire three month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 39-54 are pending in the application.
Of the above, claims ~~39-48~~ 49-51 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 39-48 and 52-54 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

5 The present examination on the merits has been performed with respect to claims 39-48, and 52-54 by original presentation. The claims 49-51 have been removed from further consideration as being drawn to a non-elected invention. See 1046 TMOG 2, September 4, 1984.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

10 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use
15 the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20 Claims 39-54 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited DNA constructs for expression of a chimeric polypeptide which is a subunit of an immunoglobulin molecule. See M.P.E.P. §§ 706.03(n) and 706.03(z).

25 Since applicants have not submitted any significant rebuttal in papers 15 or 16, rejections are maintained for reasons of record as stated in papers 5, 7, and 10, mailed November 29, 1988, May 24, 1989, and September 25, 1990, respectively.

30 Claims 39 and 54 are rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

35 Since applicants have not submitted any significant rebuttal in papers 15 or 16, rejections are maintained for reasons of record as stated in papers 5, 7, and 10, mailed November 29, 1988, May 24, 1989, and September 25, 1990, respectively.

40 The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

45 A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5 Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

10 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

15 Claims 39-48 and 52-54 are rejected under 35 U.S.C. § 103 as being unpatentable over Cabilly (L,R, or 2A) or Boss (2b) in view of Gillies(S).

20 Applicant's arguments filed May 23, 1991 and March 25, 1991 have been fully considered but they are not deemed to be persuasive.

25 Rejections are maintained for reasons of record, stated in papers 5, 7, and 10, mailed November 29, 1988, May 24, 1989, and September 25, 1990.

30 Applicant's arguments as set forth in paper 16, filed May 20, 1991, may be summarized as follows. Applicants argue that the prior art involving immunoglobulin production in mammalian cells does not demonstrate the certainty of functionally producing immunoglobulins where both immunoglobulin chains are exogenous to the host cell. Further traversal is made with respect to the inadequacy of the Cabilly references. Cabilly is alleged to be inadequate in several areas. First, applicants emphasize that the instant receptors are functionally produced and assembled in the host cell rather than reconstructed after the fact, as in Cabilly. Second, Cabilly fails to mention any of the attendant advantages of mammalian expression systems demonstrated by the instant invention. Third, the prior art shows that bacterial expression systems do not functionally assemble immunoglobulins. Finally, arguments are made comparing the lack of enablement of

the Cabilly reference when compared with the instant specification. Final arguments deal with the removal of the Boss patent from the prior art as the publication date is after the filing of the first parent application.

As regards the possibility of producing two exogenous immunoglobulin genes in a cell which does not produce immunoglobulin, the argument is not persuasive because the Cabilly references provide just such a teaching. The teaching is, however, a bacterial teaching. Nonetheless, the prior art does indeed teach the production of two immunoglobulin chains which are exogenous to the host cell expression system. The only difference between the instant invention and the prior art is now the type of host cell.

The Gillies reference solves this problem. The Gillies reference fails to teach production of two exogenous immunoglobulin chains in a host system, but ample description and enablement is provided for the functional production of immunoglobulins in mammalian hosts. Given Cabilly's explicit suggestion of mammals, one of ordinary skill in the art would have had ample motivation to combine the teachings of the Cabilly reference with the attendant advantages known to result from mammalian cell expression.

In sum, the enablement of Gillies solves applicant's concern with the mere paper reference of Cabilly. Applicant's for enablement under §35 U.S.C. 112 are far more stringent than requirements for enablement under §35 U.S.C. 102/103. So, the law demands that applicant's specification be far more explicit than the prior art (In re Lukach, 169 USPQ 795; Chester v Miller, 15 USPQ2nd 1333). Moreover, the elements of Cabilly which are lacking are in fact supplied by Gillies, therefore, the problems of functional assembly are solved as well as the attendant advantages of mammalian cell expression. Furthermore, applicants have provided evidence on pages 4 and 5 of paper No. 16, that immunoglobulin subunits were known to functionally assemble in mammalian expression systems. Therefore, the fact that one of skill in the art is specifically motivated by Cabilly to use mammalian systems and that mammalian systems were known to functionally express exogenous immunoglobulin, would render the instant invention obvious to one of ordinary skill in the art.

Finally, applicant's arguments concerning the date of the Boss reference are not considered persuasive because the claims at issue are not limited specifically to receptors that are not chimeric. Failure to specifically claim a broader embodiment is not equivalent to specifically excluding said broader embodiment. Therefore, the instant claims cannot be given the August 1984

priority because these claims read on material not disclosed in the original parent.

5 It is noted that the essential issues that remain in dispute are the same in the instant application as they have been in prior applications. Accordingly, the instant application is in condition either for appeal or abandonment.

10 This is a File Wrapper Continuation of applicant's earlier application S.N. 07/441,189. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds or art of record in the next Office action if they had been entered in the earlier application. Accordingly, THIS ACTION IS MADE FINAL even though
15 it is a first action in this case. See M.P.E.P. § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

20 A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE
25 ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

30 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Nisbet whose telephone number is (703) 308-1794. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.
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RICHARD A. SCHWARTZ
SUPERVISORY PATENT EXAMINER
ART UNIT 185